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AdvaMed
Advanced Medical Technology Association

October 28, 2005

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Re: Request for Comments; Critical Path Initiative; Developing Prevention Therapies; Planning of Workshop; Docket No. 2004N-0355

Dear Sir/Madam:

I am writing in response to the subject Request for Comments intended to assist FDA in planning a workshop to address factors relating to a new term coined in the notice: chemoprevention.

AdvaMed is the world's largest association representing manufacturers of medical devices, diagnostic products, and medical information systems. AdvaMed's more than 1,300 members and subsidiaries manufacture nearly 90 percent of the $80 billion of health care technology products purchased annually in the United States, and more than 50 percent of the $175 billion purchased annually around the world. AdvaMed members range from the largest to the smallest medical technology innovators and companies. More than 70 percent of our members have less than $30 million in domestic sales annually.

The medical device industry is again disappointed to read an FDA Critical Path document that appears to ignore the intrinsic differences between medical devices and drugs. In our initial responses to the Critical Path White Paper, we tried to make these distinctions clear. Yet, we now see another document that blurs the distinction between medical devices and drugs.

We believe that this is particularly apparent in the newly minted term, chemoprevention. The immediate inference that one draws from the term is that it envisions disease prevention resulting from the *application* in some manner of *chemicals* to the human body, either internally or externally. While medical devices may be used in this application, e.g., to inject or otherwise introduce the chemical to the body, it appears that the expected agent of change is the chemical itself.

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The Federal Register Notice describes "chemoprevention" as "prevention therapies other than lifestyle changes, dietary supplements, or dietary choices that could reduce the risk of certain illnesses" and then proposes a number of drug-focused topics for discussion at the workshop. Although the Notice begins broadly, stating FDA's intent to cover medical devices, the topics in Section III for discussion at the workshop focus narrowly on drugs. For example, question 7 does not even address medical devices. It asks, "What are some of the obstacles facing manufacturers who wish to develop new or existing *compounds* for chemoprevention? (Emphasis added)."

Medical devices play a critical role in the broad area of disease prevention. They are used to identify pathogens and other anomalies (e.g., genetic defects). They are used to deliver both drugs and vaccines, and in some cases, medical devices create a physical barrier against disease transmission. They can identify disease susceptibilities. In some cases, they may be used to guide therapy placement. Cardiovascular medical devices and *in vitro* diagnostic devices for use in the cardiovascular, cancer, and genomic fields are just a few examples of medical devices that would benefit from a discussion under the Critical Path "chemoprevention" initiative.

Medical device manufacturers also face obstacles in developing new medical devices; obstacles that can be addressed through the Critical Path. In response to FDA's Critical Path Initiative, AdvaMed submitted a number of examples of these obstacles.

We believe that FDA needs to decide whether the workshop will address all medical products or only drugs. This is not currently clear. If the intent is to address medical products more broadly, then the term chemoprevention is inadequate and the use of the term disease prevention would be more apt.

In response to FDA's request for feedback on the format of the workshop and to ensure adequate consideration of medical devices, we recommend FDA structure the workshop into separate drug and medical device sessions for both the broad perspective discussion (day one) and the breakout sessions (day two).

Thank you for the opportunity to comment on the proposed workshop. For further clarification or questions, please contact me at 202.434.7230 or bliebler@advamed.org.

Sincerely,

Bernie Liebler
Director
Technology and Regulatory Affairs